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### **FW**

#### **I agree with the value of morality.**

#### **The standard is maximizing expected well-being.**

#### **Pleasure and pain are the starting point of all moral reasoning.**

**Moen, 16** Ole Martin (PhD, Research Fellow in Philosophy at University of Oslo). "An Argument for Hedonism." Journal of Value Inquiry 50.2 (2016): 267.

Let us start by observing, empirically, that **a widely shared judgment about intrinsic value** and disvalue **is that pleasure is intrinsically valuable and pain is intrinsically disvaluable**. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels**, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” **are** here **understood inclusively**, as encompassing anything hedonically positive and anything hedonically negative. 2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store**, I might ask: “What for**?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. **The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good**. 3 As Aristotle observes: “**We never ask** [a man] **what** his **end is in being pleased, because we assume that pleasure is choice worthy in itself**.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that **if something is painful, we have a sufficient explanation of why it is bad**. If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value. Although pleasure and pain thus seem to be good candidates for intrinsic value and disvalue**.

**Prefer Additionally:**

**1) In situations of moral uncertainty, preventing extinction should always come first.**

**Bostrom, 12** Nick Bostrom (Faculty of Philosophy & Oxford Martin School University of Oxford). “Existential Risk Prevention as Global Priority.” Global Policy 2012.

These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate. Our present understanding of axiology might well be confused. **We may not now know — at least not in concrete detail — what outcomes would count as a big win for humanity**; we might not even yet be able to imagine the best ends of our journey. **If we are** indeed profoundly **uncertain about our ultimate aims, then we should recognize that there is a great option value in preserving** — and ideally improving — our ability to recognize value and to steer the future accordingly. Ensuring that there will be **a future version of humanity** with great powers and a propensity to use them wisely is plausibly **the best way available to us to increase the probability that the future will contain a lot of value**. To do this, **we must prevent any existential catastrophe.**

**2) Actor Specificity: Util is the only moral system available to policymakers.**

**Goodin, 90** Robert Goodin, fellow in philosophy, Australian National Defense University, The Utilitarian Response, 1990, p. 141-2

My larger argument turns on the proposition that there is something special about the situation of public officials that makes utilitarianism more probable for them than private individuals. Before proceeding with the large argument, I must therefore say what it is that makes it so special about public officials and their situations that make it both more necessary and more desirable for them to adopt a more credible form of utilitarianism. Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices – public and private alike – are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. **Public officials**, in contrast, [they] **are relatively poorly informed as to the effects that their choices will have on individuals, one by one**. **What they typically do know are generalities**: averages **and aggregates.** They know what will happen most often to most people as a result of their various possible choices, but that is all. **That is enough to allow[s] public policy-makers to use** the **util**itarian calculus – assuming they want to use it at all – to chose general rules or conduct.

#### **3. Util is a lexical prerequisite to any other framework, because threats to bodily security and life preclude the ability for moral actors to effectively utilize other moral theories.**

4.  **Only consequentialism explains degrees of wrongness if I break a promise to meet up for lunch, that is not as bad as breaking a promise to take a dying person to the hospital. Only the consequences of breaking the promise explain why the second one is much worse than the first.**

#### 5. Ground—all impacts matter under Util while other ethical frameworks exclusively flow one side or another, means there isn’t equitable ground—reciprocal ground is key to fairness, its definitionally giving equal access to both debaters

#### 6. Topic Lit—most articles are written by economists and politicians for the general public that cares about consequences, which means util allows for the most topic research, which is key to fairness, it’s the only way for us to generate in round prep to win debates.

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#### 7. Real World Applicability—util is key to learn about politics and our government and how policymakers work, even if they are oppressive or bad, our framework is the most educational in teaching us about how things operate in the real world, which outweighs all other impacts because it’s the only portable out of round skill

### **Pharma Retaliation DA**

#### **Reducing IPR protections may result in backlash from pharmaceutical companies risking lives**

**Lazare and Guerrero 2021** [Sarah, editor and reporter, journalist, In These Times, "Big Pharma Is Deciding Who Lives and Who Dies in the Global South The chilling effect of the pharmaceutical industry’s veiled threats." July 22, https://inthesetimes.com/article/pfizer-pharmaceutical-companies-covid-pandemic-coronavirus-latin-america-trips-waiver-vaccines

On April 24, Elizabeth de Carvalhaes, executive president of the Brazilian pharmaceutical company trade group Interfarma, said out loud what the drug industry had up until then avoided uttering in public. In an interview with Folha de São Paulo, the most widely-read newspaper in Brazil, de Carvalhaes declared that if the South American country were to green-light compulsory licensing to expand access to Covid-19 vaccines, pharmaceutical companies might respond by withholding supply of the vaccines. ​“This is not retaliation,” she proclaimed. ​“The demand is much bigger than the supply, and they may find it more advantageous from an economic point of view to sell to countries that do not break patents.”

This was not an idle threat. Interfarma represents Pfizer, Gilead, AstraZeneca and other major pharmaceutical companies. The trade group’s spokesperson made the remarks at a time when Brazil was pushed to the point of desperation: The same day the article was published, more than 71,000 new Covid-19 cases were reported in Brazil. The country’s outbreak has been so severe and uncontrolled that it’s spawned the Gamma variant, which has since spread around the world.

Some countries hope to find relief in compulsory licensing, when a government allows the production of a vaccine without the consent of a patent owner, a move floated in Brazil as a way to urgently expand vaccine access while the pandemic rages. (A compulsory licensing bill has passed Brazil’s Senate but has not yet officially been signed into law.)

Interfarma’s implied threat against such a measure underscores a dynamic that public health advocates say is particularly pernicious during a pandemic: Countries that run afoul of drug companies by supporting measures to override patents risk facing the wrath of an industry that has the power to decide whether a huge swath of their population lives or dies.

#### **Pharmaceutical companies have retaliated in the past when IPR has been eased.**

**Lazare and Guerrero 2021** [Sarah, editor and reporter, journalist, In These Times, "Big Pharma Is Deciding Who Lives and Who Dies in the Global South The chilling effect of the pharmaceutical industry’s veiled threats." July 22, https://inthesetimes.com/article/pfizer-pharmaceutical-companies-covid-pandemic-coronavirus-latin-america-trips-waiver-vaccines

This would not be the first time the pharmaceutical industry has retaliated against countries. In 2007, the U.S.-based Abbott Laboratories refused to supply Thailand with a new HIV treatment in response to the country’s decision to override patent rules on three drugs the company produces, including a cheaper, generic version of the HIV treatment Kaletra. Abbott deliberately withheld a new heat-stable version of Kaletra, which is best suited for countries with hot, muggy climates, and the company was explicit about its punitive intent. ​“This is a consequence, directly, of the Thai government’s decision not to support innovation by breaking the patents of numerous medicines,” said Dirk van Eeden, director for Abbott’s public affairs, according to a 2007 article in Financial Times. (A few weeks later, Abbott reversed its decisions following global outcry.)

But one can look to more recent history to find other forms of industry retaliation. As journalist Lee Fang reported in March, pharmaceutical industry trade groups pressured the Biden administration to impose sanctions on Hungary, Chile and Colombia for their efforts to override patent rules in a bid to improve access to Covid-19 vaccines. This kind of retaliation is not new or unique to the Covid-19 pandemic. Pharmaceutical companies and American lawmakers have threatened India with sanctions for its production of a cheaper version of a cancer drug, and threatened Malaysia with sanctions for its use of a cheaper version of a Hepatitis C drug. Such actions can have a chilling effect. ​“As a result of these and other instances, countries have, understandably, been reluctant to develop more flexible domestic [compulsory licensing] policies and are certainly out of practice in using them,” writes Rachel Thrasher, research fellow at the Global Development Policy Center.

## ***Innovation da***

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#### **IPR is the backbone of innovation, but threat of restrictions such as compulsory licensing imperil it**

#### **DeRoo 11**

#### Pier DeRoo (J.D. Candidate 2011, University of Michigan Law School; A.B. 2006, Chemistry, Princeton University). “Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Go Pharmaceutical Drugs in Government Health Car ernment Health Care Programs.” Michigan Journal of International Law, vol. 32, issue 2. 2011. JDN. https://repository.law.umich.edu/mjil/vol32/iss2/3/

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#### The Pharmaceutical Development Outlook

#### Government health care programs, however, when combined with compulsory licensing and important pharmaceutical markets, represent a corresponding threat to the current R&D infrastructure of drug development, which is funded both by purchasers of pharmaceutical products and by taxpayers via public research entities. With **only one of every 5,000**-10,000 **tested compounds** reaching the market and taking an average of **11**.8 **years to get there**, drug R&D investment requires a high risk premium. Although the exact amount is disputed, current estimates to develop an innovative, new molecular entity drug range from $802-$868 million, and costs continue to rise. o0 Pharmaceutical development is also far from a purely private enterprise, with the NIH annually spending over $31 billion in taxpayer dollars in basic medical research, which supports downstream drug development by the pharmaceutical industry.'o4 R&D therefore usually targets drugs that have an expected return high enough to generate substantial profit and fund subsequent R&D. Because R&D investment decisions are guided by the expected economic return for a particular line of research, **palatability of risk is proportional to** the **magnitude of** the **expected returns.**'" Assuming that research into risky, unexplored areas of health is desirable, low expected returns, whether due to a small market for a particular drug or weakened patent exclusivity rights as a result of **compulsory licensing**, may chill such R&D. After a pharmaceutical drug runs the gamut of patenting, clinical trials, and regulatory approval procedures, the patent specification and a wealth of safety and efficacy data are available to the public, resulting in **serious appropriability concerns.**' In the absence of strong patent protection and regulatory data exclusivity, generic producers are able to rapidly reverse-engineer drugs, obtain regulatory approval by relying on the patent holder's safety and efficacy data, and sell the generic version on a competitive market against the innovative firm that incurred the stratospheric R&D and original regulatory approval costs.0o Without such protection, the innovative pharmaceutical developer could expect little return on investment, and private R&D would dissipate. Indeed, pharmaceutical appropriability in India resulted in a commodified Indian pharmaceutical market devoid of R&D. In the Indian Patents Act of 1970, India abolished pharmaceutical compound patentability in favor of short seven-year pharmaceutical production-process patents, creating incentives to devise increasingly efficient production processes while permitting any manufacturer to produce the pharmaceutical compound itself.'" Drug **firms flooded the market** as the number of licensed manufacturers grew from 2,237 enterprises in 1969-70 to an estimated 16,000 by 1992-93, illustrating that barriers to entry into the pharmaceutical market were not onerous. Profitability predictably plunged over that period, reducing R&D expenditures from 15.5% of sales prior to the 1970 Patents Act to a **mere 1**.4**%** in 1992-93 because of comparative declines in expected returns on R&D investment due to the absence of exclusivity for drug compounds.'" 1.4% does not fund much R&D: India has become the world's leading generic pharmaceutical producer, but contributes little to the development of new pharmaceutical medicines."2 The most powerful developing countries followed India in prohibiting patent protection for pharmaceuticals. Between 1971 and 1996, Brazil prohibited patents for both pharmaceutical products and processes."' Mexico and Argentina had similarly lowered pharmaceutical patent protection prior to TRIPS." 4 As a result, today only a handful of developed countries have a sufficiently sophisticated pharmaceutical industry and research base to conduct complex R&D. Compulsory licensing, if widely used as an escape-hatch from patent protection, presents a potential threat to continued research by relegating innovative producers to a level playing field with generic producers.' Once a compulsory license is granted, licensees simply have to send a royalty check to the patent holder.7 These royalty payments are uniformly puny. For example, Indonesia offered a mere **0.5%** royalty on the generic sale price for its HIV/AIDS compulsory licenses,"' Zambia offered 2.5%,"' and Mozambique offered 2%.120 Meanwhile, Thailand has offered 0.5% to 2.0%.121 The pharmaceutical market has already encountered the likely bleak effects of widespread compulsory licensing and its low royalty rates. The post-1970 Indian pharmaceutical industry demonstrated that extremely low margins do not incentivize R&D.122 In a similar vein, the Egyptian pharmaceutical industry is currently discovering that its cost-plus pricesetting system, using the costs of ingredients as the benchmark, establishes a profit ceiling that acts as a de facto limit on R&D expenditures.123 Limiting economic returns on pharmaceutical R&D through abusive compulsory licensing, especially if in one or more of the few countries with innovative pharmaceutical industries,'2 **therefore poses a threat to continued R&D** into unexplored areas of medicine.

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#### Innovation cannot happen without IP protections—five warrants.

#### **McDole and Ezell '21** (Jaci Mcdole and Stephen Ezell; McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation (ITIF). Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.; 4-29-2021; "Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic"; https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through, ITIF, accessed 7-29-2021; JPark)

#### A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, **positive correlation between IP rights and economic performance**.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID-19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation. There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike.31 **First,** stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives.32 Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.33 There’s also evidence suggesting that **developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines.**34 And fifth, **strong IP boosts exports**, including **in developing countries**.35 **Research shows a positive correlation between stronger IP protection and exports from developing countries** as well as faster growth rates of certain industries.36

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#### **Independently, medical innovation turns the aff—their ‘flexible’ provisions are useless without the necessary domestic infrastructure to employ them**

#### **Halaijan 13**

#### Dina Halaijan (JD, Brooklyn Law School). “Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem.” Brooklyn Journal of International Law. Volume 38, Issue 3, Article 7 (2013). JDN.<https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1050&context=bjil>

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#### 4. Limitations Inherent in Developing Countries

#### Another impediment to the successful use of the TRIPS flexibilities and the successful achievement of its dual goals is the endemic and inherent characteristics of developing countries. Taking advantage of TRIPS flexibilities requires **tech**nical **expertise**, **intergovernmental coordination**, and **legal sophistication**, which are often lacking in developing governments.129 Thus, TRIPS flexibilities often do not benefit the least developed countries most in need of help, and rather help middle income countries such as India and Brazil.130 Developing countries also lack **proper disease diagnosis** capabilities, which hinders their ability to request proper quantities and types of medications in a compulsory license.131 Developing governments have been criticized for mass military spending when there are existing public health issues, and so they may need to reevaluate their priorities.132 Developing countries and their citizens may choose to spend funds on food rather than medication, even if costs are reduced, if insufficient funds exist to cover both costs.133 Additionally, some developing governments are **corrupt** and may resell medications at higher prices, rather than distributing the drugs to their citizens.134 A “scrupulous clean hands approach” must be practiced to ensure drugs are actually distributed at the lowest profitable prices, and unfortunately such practices have been questionable.135 Further, lobbying pressure and conflicting interests may create abusive overuse of compulsory licensing where, for example, “the chairman of a large generic drug manufacturer was also the Chairman of the Health Committee in Egypt’s upper house of Parliament at the time the [Viagra] compulsory license was issued [in Egypt].”13

#### **Innovation necessary to solve future pandemics, antimicrobial diseases, and bioterror.**

#### **Marjanovic and Fejiao 20** Marjanovic, Sonja, and Carolina Feijao. SonjaMarjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020).

#### As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but **there are many others.** For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. **Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.**1 The general threat to public health that is posed by **antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation.** Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and **infrastructure that industry has** within its reach, as well as public expectations and the moral imperative, **make pharmaceutical companies** and the wider life sciences sector **an indispensable partner** in the search for solutions that save lives. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 **Pharmaceutical companies are collaborating with each other** in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions. Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with **other infectious diseases, bioterrorism agents and antimicrobial resistance**) **are urgently in need of pharmaceutical innovation**, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions. The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate industry efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would qualify as an immediate crisis (e.g. growing risks of antimicrobial resistance to some infectious pathogens). However, **such diseases and issues are recognised as global threats that could become crises in the future.**

#### **Bioterrorism and antimicrobial diseases lead to extinction – modern technologies can be used to isolate deadly pathogens and target vast populations.**

#### **Kellman ‘08** (Barry, Professor of Law, Director, International Weapons Control Center, International Human Rights Law Institute @ DePaul U., Futurist, May 2008, “Bioviolence: A Growing Threat,” http://www.britannica.com/bps/additionalcontent/18/31535413/Bioviolence-A-Growing-Threat)

#### According to the National Academies of Science, "The threat spectrum is broad and evolving – in some ways predictably, in other ways unexpectedly. In the future, genetic engineering and other technologies may lead to the development of pathogenic organisms with unique, unpredictable characteristics." For as far into the future as we can possibly see, every passing day it be- comes slightly easier to commit a vio lent catastrophe than it was the day before. Indeed, the rapid pace of advancing science helps explain why policies to prevent such a catastrophe are so complicated. Bioviolence Jihad? Some experts argue that terrorists and fanatics are not interested in bio- violence and that the danger might therefore be overblown. Since there have been no catastrophic bioviolence attacks, these experts argue, terrorists lack the intention to make bioweapons. Hopefully, they are correct. But an enormous amount of evidence suggests they are wrong**. From** **the dawn of biology's ability to isolate pathogens, people** have **pursued hostile applications of bio**logical **agents**. It is perilous to ignore this extensive history by presuming that today's villains are not fervent about weaponizing disease. Not a single state admits to having a bioweapons program, but U.S. intelligence officials assert that as many as 10 states might have active programs, including North Korea, Iran, and Syria. Moreover, many **terrorist organizations have expressed interest** in acquiring biological weapons. Whatever weight the taboo against inflicting disease might have for nation-states, it is obviously irrelevant to terrorists, criminals, and lunatics. Deterrence by threat of retaliation is essentially meaningless for groups with suicidal inclinations who are likely to intermingle with innocent civilians. Al-Qaeda and affiliated Islamic fundamentalist organizations have abling them to spread in regions where there is no natural immunity. The **polio** virus **has been synthesized from scratch**; its creators called it an "animate chemical." Soon, it may be resynthesized into a form that is contagious even **among vaccinated populations**. Recreation of long-eradicated livestock diseases could **ravage herds** severely lacking in genetic diversity, **damage food supplies, and cause devastating economic losses**. Perhaps the greatest biothreat is the manipulation of the flu and other highly contagious viruses, such as Ebola. Today, scientists can change parts of a virus's genetic material so that it can perform specific functions. The genomic sequence of the Spanish flu virus that killed upwards of 40 million people nearly a century ago has been widely published; **any** savvy **scientist could reconstruct it**. The avian flu is even more lethal, albeit not readily contagious via casual aerosol delivery. A malevolent bio- scientist might augment its contagiousness. The Ebola virus might be manipulated so that it kills more slowly, allowing it to be spread farther before its debilitating effects al- together consume its carrier. A bit further off is genetic manipulation of the measles virus--one of the great killers in human history--rendering useless the immunizations that most of us receive in early childhood. Soon, laboratory resynthesis of smallpox may be possible. Advanced drug delivery systems can be used to **disseminate lethal agents to broad populations**. Bio- regulators--small organic compounds that modify body systems-- could enhance targeted delivery technologies. Some experts are concerned that new weapons could be aimed at the immune, neurological, and neuroendocrine systems. Nanotechnology that lends itself to mechanisms for advanced disease detection and drug delivery--such as gold nanotubes that can administer drugs directly into a tumor--could also de- liver weaponized agents deep into the body, substantially raising the weapon's effectiveness. Altogether, techniques that were on the frontiers of science only a dec- ade or two ago are rapidly mutating A looming danger confronts the world--the threat of bioviolence. It is a danger that will only grow in the future, yet we are increasingly failing to confront it. With every passing day, committing a biocatastrophe becomes a bit easier, and this condition will perpetuate for as long as science progresses. Biological warfare is as old as conflict, of course, but in terms of the objectives of traditional warfare-- gaining territory or resources, compelling the surrender of an opposing army--biological weapons weren't very effective. If the objective is to inflict mass death and panic on a mixed population, however, emerg- ing bioweapons offer remarkable potential. We would be irresponsible to presume that radical jihadists like al- Qaeda have ignored said potential.

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### AT Patents

#### Patents don’t increase medicine prices – turns the aff because prices don’t go down but R&D does

**Goans ‘03**

Judy Winegar Goans is a registered patent attorney. For the past twenty years, she worked in development assistance, providing legislative drafting and other assistance to help countries strengthen their intellectual property systems and prepare for membership in the World Trade Organization. She is the author of Intellectual Property Principles and Practice, a comprehensive intellectual property text that has been used in several countries. Ms. Goans is admitted to practice in Tennessee and before the Court of Appeals for the Federal Circuit and U.S. Supreme Court. She previously worked with a Washington-area consulting firm; the Office of Legislation and International Affairs in the U.S. Patent and Trademark Office; and the U.S. Department of Energy. Among her accomplishments, she helped Egypt's Patent Office become a PCT International Search and Preliminary Examination Authority and the Lao People's Democratic Republic strengthen its legal framework on intellectual property so that it qualified for membership in the World Trade Organization. She is currently consulting on intellectual property issues in Myanmar and volunteering with Bridge Refugee Services. Ms. Goans has served as Editor-in-Chief of the IP Section newsletter since 2012. 2003 “Intellectual Property and Developing Countries “[https://www.hsdl.org/?view&did=446296#:~:text=At%20the%20macroeconomic%20level%2C%20intellectual,activities%20of%20the%20developed%20world.]

The **greatest obstacle to enacting stronger** **i**ntellectual **p**roperty **laws** **is the fear that** **[it]** adopting

intellectual property protection **will increase prices**, particularly **for medicines**. Compared

with older technology, new products may indeed be more expensive, whether or not they are

patented. **It does not follow**, **however**, **that introducing patent** protection **will cause** an

**increase in prices**. A **study** commissioned by an association of research-based pharmaceutical

companies **found that adopting patent protection for pharma**ceutical products **did not result**

**in** an **increase in** pharmaceutical **prices in** the **countries** studied.17 This is not surprising

because **patents apply only prospectively**. Products that are already on the market are

unaffected by the introduction of a patent law. In most countries, **off-patent pharmaceuticals**

**account for more than 90 percent of the legitimate drugs** on the market. **When** a **new product**

**is introduced, it does not replace existing products but is added to the choices available**. If it

offers benefits over other products, consumers may be willing to purchase it, even at a higher

price—or they may continue to use existing, unpatented items.

**The argument that intellectual property will increase prices is** often **advanced to support**

permitting the **sale of generic drugs**. Because **a manufacturer of generic products** **does not**

**have to** recover an initial **invest**ment **in r**esearch **and** **d**evelopment, it may **offer products at a**

**lower price.** **Generic products** are sold within the framework of a patent system, and a

thriving generic drug industry **often exist**s **side by side with research-based pharma**ceutical

companies in countries with strong patent protection. **Care should be exercised to distinguish**

**between this situation and the failure to provide patent protection—in a sense making all**

**products “generic”—or sales of infringing products.**

#### **Antimicrobial development needs to be further developed, only innovation solves**

#### **Jacome ‘19** Esaú López-Jácome, Rafael Franco-Cendejas, Héctor Quezada, Rosario Morales-Espinosa, Israel Castillo-Juárez, Bertha González-Pedrajo, Ana María Fernández-Presas, Arturo Tovar-García, Vanesa Angarita-Zapata, Paula Licona-Limón, Mariano Martínez-Vázquez, Rodolfo García-Contreras,

#### The race between drug introduction and appearance of microbial resistance. Current balance and alternative approaches,

#### Current Opinion in Pharmacology,

#### Volume 48,

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#### (https://www.sciencedirect.com/science/article/pii/S1471489218301723)

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#### **Current levels of antimicrobial resistance are alarming** [1] and the projections indicate that **if no new effective antimicrobials are introduced, by the year 2050 there will be more deaths caused by multidrug resistant**(MDR) **bacteria** (MDR) **than by current leading causes of death including cancer** [2]. The most recent World Health Organization’s (WHO) review about antibiotic resistance announced a global priority pathogens list, classifying the bacteria depending on priority in critical, high and medium. The majority of infectionsin hospitals are caused by ‘ESKAPE’ pathogens (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa and Enterobacter spp.) [3,4]. Antibiotics interfere with essential bacterial processes such as cell wall, protein, and nucleic acid synthesis, interrupting DNA replication, disrupting membrane integrity and important metabolic pathways, either killing or arresting bacterial growth,therefore exerting an intense selection pressure for the development ofresistance. Since the introduction of penicillin in the early 1940’s,the selection of resistant bacteria is typical and the percentage of **resistant strains against multiple antibiotics** and even to all **is increasing.**

#### **Bioterrorism leads to extinction – modern technologies can be used to isolate deadly pathogens and target vast populations.**

#### **Kellman ‘08** (Barry, Professor of Law, Director, International Weapons Control Center, International Human Rights Law Institute @ DePaul U., Futurist, May 2008, “Bioviolence: A Growing Threat,” http://www.britannica.com/bps/additionalcontent/18/31535413/Bioviolence-A-Growing-Threat)

#### According to the National Academies of Science, "The threat spectrum is broad and evolving – in some ways predictably, in other ways unexpectedly. In the future, genetic engineering and other technologies may lead to the development of pathogenic organisms with unique, unpredictable characteristics." For as far into the future as we can possibly see, every passing day it be- comes slightly easier to commit a vio lent catastrophe than it was the day before. Indeed, the rapid pace of advancing science helps explain why policies to prevent such a catastrophe are so complicated. Bioviolence Jihad? Some experts argue that terrorists and fanatics are not interested in bio- violence and that the danger might therefore be overblown. Since there have been no catastrophic bioviolence attacks, these experts argue, terrorists lack the intention to make bioweapons. Hopefully, they are correct. But an enormous amount of evidence suggests they are wrong**. From** **the dawn of biology's ability to isolate pathogens, people** have **pursued hostile applications of bio**logical **agents**. It is perilous to ignore this extensive history by presuming that today's villains are not fervent about weaponizing disease. Not a single state admits to having a bioweapons program, but U.S. intelligence officials assert that as many as 10 states might have active programs, including North Korea, Iran, and Syria. Moreover, many **terrorist organizations have expressed interest** in acquiring biological weapons. Whatever weight the taboo against inflicting disease might have for nation-states, it is obviously irrelevant to terrorists, criminals, and lunatics. Deterrence by threat of retaliation is essentially meaningless for groups with suicidal inclinations who are likely to intermingle with innocent civilians. Al-Qaeda and affiliated Islamic fundamentalist organizations have abling them to spread in regions where there is no natural immunity. The **polio** virus **has been synthesized from scratch**; its creators called it an "animate chemical." Soon, it may be resynthesized into a form that is contagious even **among vaccinated populations**. Recreation of long-eradicated livestock diseases could **ravage herds** severely lacking in genetic diversity, **damage food supplies, and cause devastating economic losses**. Perhaps the greatest biothreat is the manipulation of the flu and other highly contagious viruses, such as Ebola. Today, scientists can change parts of a virus's genetic material so that it can perform specific functions. The genomic sequence of the Spanish flu virus that killed upwards of 40 million people nearly a century ago has been widely published; **any** savvy **scientist could reconstruct it**. The avian flu is even more lethal, albeit not readily contagious via casual aerosol delivery. A malevolent bio- scientist might augment its contagiousness. The Ebola virus might be manipulated so that it kills more slowly, allowing it to be spread farther before its debilitating effects al- together consume its carrier. A bit further off is genetic manipulation of the measles virus--one of the great killers in human history--rendering useless the immunizations that most of us receive in early childhood. Soon, laboratory resynthesis of smallpox may be possible. Advanced drug delivery systems can be used to **disseminate lethal agents to broad populations**. Bio- regulators--small organic compounds that modify body systems-- could enhance targeted delivery technologies. Some experts are concerned that new weapons could be aimed at the immune, neurological, and neuroendocrine systems. Nanotechnology that lends itself to mechanisms for advanced disease detection and drug delivery--such as gold nanotubes that can administer drugs directly into a tumor--could also de- liver weaponized agents deep into the body, substantially raising the weapon's effectiveness. Altogether, techniques that were on the frontiers of science only a dec- ade or two ago are rapidly mutating A looming danger confronts the world--the threat of bioviolence. It is a danger that will only grow in the future, yet we are increasingly failing to confront it. With every passing day, committing a biocatastrophe becomes a bit easier, and this condition will perpetuate for as long as science progresses. Biological warfare is as old as conflict, of course, but in terms of the objectives of traditional warfare-- gaining territory or resources, compelling the surrender of an opposing army--biological weapons weren't very effective. If the objective is to inflict mass death and panic on a mixed population, however, emerg- ing bioweapons offer remarkable potential. We would be irresponsible to presume that radical jihadists like al- Qaeda have ignored said potential.

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### Ambiguity

#### TRIPS alone is too ambiguous to serve as a sufficient legal standard

**Halaijan 13**

Dina Halaijan (JD, Brooklyn Law School). “Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem.” Brooklyn Journal of International Law. Volume 38, Issue 3, Article 7 (2013). JDN. <https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1050&context=bjil>

3. Definitional Ambiguities & Ambiguities in Scope

Ambiguities in the interpretation of TRIPS due to the lack of substantive guidelines or definitions also hinder its effective use by **increasing the risk of litigation.**111 The Doha Declaration merely stated that individual countries have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency” in deciding to grant a compulsory license, and thus did little to ameliorate the different interpretive approaches of developed and developing countries.112 **The flexible scope** of compulsory licenses **lends to abuse which further instills resistance and suspicion** from pharmaceutical companies.113 For example, Egypt’s compulsory license for Pfizer’s Viagra tarnishes the reputation of compulsory licensing because erectile dysfunction is clearly a less dire situation and one likely not intended to be covered by the public health exception of TRIPS.114 Such excessive abuse and over-use of compulsory licensing likely encourages pharmaceutical companies to aggressively resist valid uses of compulsory licenses to prevent **over-expansion of scope.**115 In addition to ambiguity in the scope of intended diseases, conflicting interpretations exist in the type of pharmaceutical products intended for compulsory licensing.116 The scope of countries that should benefit from compulsory licensing remains another area of contention.117 Not limiting the scope of applicable nations may create a **chilling effect** on the types of drugs pharmaceutical companies choose to invest in and develop to avoid the potential for a compulsory license, **which hurts developing nations most in need of help.**118 Interpreting the morality exclusion in Article 27(2) also proves difficult, as **there is no universally accepted definition.**119 In addition to causing differing interpretations between countries, the lack of concrete definitions allows countries to alter their position to fit their self-interest and creates potential for abuse.120 For example, despite the United States’ narrow interpretation of TRIPS flexibilities, the United States contradicted itself during the 2001 anthrax scare by suggesting use of a compulsory license for Cipro, a drug that combats the effects of anthrax.121 On a related note, as India’s government and pharmaceutical industry’s capabilities grow, the future of India’s willingness to grant compulsory licenses and produce cheap generic drugs for export to other developing countries is questionable.122 Indian companies may opt to serve their selfinterest and become “innovator companies” to compete globally with other large pharmaceutical companies.123 The vagueness of Article 30, which allowed a narrow interpretation to be given by the WTO dispute resolution panel, is a further impediment to increasing access to medicines.124 Calculating adequate remuneration for payment to the patent holder when a compulsory license is issued is another obstacle to successful use of TRIPS flexibilities and is further complicated by the requirement to take the economic value of the authorization into account, as TRIPS does not provide guidance to determine what is ‘adequate’ and what is the authorization’s ‘value.’125 The WTO members’ inability to reach a decision regarding parallel importation created a “fundamental flaw” of ambiguity.126 In regard to compulsory licensing under the Paragraph 6 Decision, drugs made for export must be distinguishable by special labels, colors, or shapes to prevent trade diversion.127 However, lack of monitoring guidelines and repercussions makes the re-exportation issue troubling.128

### Parallel Imports

#### Restricting parallel imports is good—it reduces both inaccessibility and corruption

**Halaijan 13**

Dina Halaijan (JD, Brooklyn Law School). “Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem.” Brooklyn Journal of International Law. Volume 38, Issue 3, Article 7 (2013). JDN. <https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1050&context=bjil>

3. Parallel Importation

In addition to the compulsory license, another significant TRIPS flexibility is the concept of parallel importation alluded to in Article 6.63 Parallel importation results from price discrimination, where a particular product is sold at different prices in different countries, and is based on the concept of exhaustion.64 Exhaustion, or the first sale doctrine, states that after a sale the prior possessor of a product relinquishes all rights to the product and the new possessor is able to distribute and import it at will.65 Opponents of exhaustion, including pharmaceutical companies, contend that it “decreases profitability and **removes the incentive to sell drugs to poor countries at lower prices.**”66 Further, there is a concern that some **corrupt governments** of developing countries may resell the discounted drugs received at higher profits to other countries, rather than provide the discounted drugs to their citizens in need.67 TRIPS neither bans nor authorizes parallel importation.68

### Data Exclusivity

#### Data exclusivity is necessary to ensure effective clinical research

**Bing 21**

Dr. Han Bing (senior research fellow at the Institute of World Economics and Politics of Chinese Academy of Social Sciences). “TRIPS-plus Rules in International Trade Agreements and Access to Medicines: Chinese Perspectives and Practices.” Global Development Policy Center, Global Economic Governance Iniative. GEGI Working Paper 049, April 2021. JDN. https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf

Undisclosed test or other data refer to the data obtained in the entire medicine development process to demonstrate the medicine’s safety, efficacy and quality. The medicines and healthcare products regulatory agencies in various countries analyze and evaluate whether to approve the marketing of a new medicine based on such data. Since it is obtained from scientific studies, undisclosed test or other data are unable to satisfy the requirements of patent grant and cannot be protected by patent rights. However, the cost of obtaining marketing approval is expensive and the first registrant needs to be significant to overcome the negative price effects of competition from pharmaceutical manufacturers that free ride on the initial registrant’s marketing approval. Therefore, it is argued that, without a period of monopoly, the new drug developers will have no incentive to “conduct the costly clinical research and trials necessary to obtain marketing approval” (Chow and Lee 2018). Given its importance to the pharmaceutical industry, the United States is a strong proponent of adding such a provision in the TRIPS Agreement (Chow and Lee 2018). However, since the TRIPS Agreement was formally implemented 25 years ago, WTO members had not yet unified their opinions on the application of this provision. The United States, the European Union, and some members argue that, taking into account the considerable amount of efforts and costs for generating the necessary data, unless permitted by the originator, undisclosed test or other data should be granted exclusive rights against disclosure for a specific period of time (UNCTAD & ICTSD 2013, 613-615). During the period, government agencies shall not only protect such data against disclosure, but also prevent generic drug manufacturers from relying upon the data to obtain marketing approval. Developing countries such as Argentina, Brazil, India, and Thailand provide a non-exclusive protection on undisclosed test or other data, that is, such data are protected against unfair commercial use, but not granted exclusive rights, which allows government agencies to rely on such data to approve the marketing of generic medicines (UNCTAD & ICTSD 2013, 615-616). Developing countries believe that if the US and European practices were adopted, the marketing of generic medicines would be delayed, thereby unreasonably restricting the public access to medicines (UNCTAD & ICTSD 2013, 621). Prior to accession to the WTO in 2001, there were no data exclusivity provisions in China. After joining the WTO, China has assumed the obligation to protect such data in compliance with the TRIPS Agreement. Unlike most WTO members, as a condition for accession to the WTO, China agreed to provide data exclusivity protection for a period of six years (Feng 2010). Included in the Part V “Trade-Related Intellectual Property System” of the Report of the Working Party on the Accession of China (World Trade Organization 2001), China reiterated the content of and added what is not stipulated in Article 39(3) of the TRIPS Agreement. That is, during the period of six years, China does not allow approval of marketing for generic medicines, in order to provide exclusive protection for undisclosed test or other data of new chemical entities (World Trade Organization 2001, 284). Moreover, such protection is independent of patent protection, which means such data are protected whether a medicine is granted patent or not. The period of six years exclusive protection for undisclosed test or other data is longer than the period of 5 years of protection in the US and a number of bilateral free trade agreements.

### A/T IPR cause of medicine inequality

#### IPR is not the cause of medicine inequality. Multiple alternative causes exist

**Haugen 2021** [Hans Morten, Professor of International Diakonia at the VID Specialized University, Oslo, Norway, The Journal of World Intellectual Property, "Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good?" March 18, https://onlinelibrary.wiley.com/doi/10.1111/jwip.12187

This article analyzes the context for the allegation that IP is among the crucial factors in promoting health innovation globally, and not preventing the universal and equitable access to vaccines, even if supply of medicines is held by developed countries to be “difficult” (WTO Secretariat, 2020a). Biotechnology actors expressed criticism of the UN High-level Panel on Access to Medicines (2016), arguing that IP tends to be overemphasized in debates over access to medicines, ignoring the wider context of what impedes such access (International Council of Biotech Associations [ICBA], 2016; Biotechnology Innovation Organization [BIO], 2016). Hence, developed countries and biotech associations concur in identifying weak funding of health care and lack of manufacturing capacity as constituting the core of the problem of access (WTO Secretariat, 2020a; see also U.S. Department of State, 2016), as well as regulatory inefficiencies, trade policies and inadequate health insurance (ICBA, 2016).

### Safeguards

#### China demonstrates that safeguards are possible—reject their assumption that FTAs are inherently exploitative

**Bing 21**

Dr. Han Bing (senior research fellow at the Institute of World Economics and Politics of Chinese Academy of Social Sciences). “TRIPS-plus Rules in International Trade Agreements and Access to Medicines: Chinese Perspectives and Practices.” Global Development Policy Center, Global Economic Governance Iniative. GEGI Working Paper 049, April 2021. JDN. https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf

CHINA’S PRACTICES TO REDUCE THE POTENTIAL NEGATIVE IMPACT OF TRIPS-PLUS RULES ON ACCESS TO MEDICINES

Although China had considered introducing pharmaceutical-related TRIPS-plus rules prior to the Phase One Agreement, there were differences in content from the Phase One Agreement. Furthermore, the Phase One Agreement provides detailed regulations on the patent term extension and patent linkage system. These systems may extend the monopolization period of the original drug and affect access to medicines. Hence, China has taken the following countermeasures to balance the tension between high standards of IPR protection rules and public health. First, China has taken full advantage of the flexibility of the Phase One Agreement to design related systems to avoid abuse of the system. For instance, in terms of patent term extension in the Phase One Agreement, the first two paragraphs of Article 1.12 provide for a patent term extension system, and the third paragraph provides that “The United States affirms that existing US measures afford treatment equivalent to that provided for in this Article.” Hence, when China transforms the provisions of the Phase One Agreement into domestic law, it is necessary to confirm the specific provisions of the existing US measures. Under the Phase One Agreement, the patent term extension system to be established by China shall at least be applicable to “a patent covering a new product, its approved method of use, or a method of making the product.” However, the extension of the patent term required under the Phase One Agreement provides no limitations that can be found under US law where the extension to compensate for delays in the marketing approval procedures applies to only one patent per product (35 U.S. Code § 156 n.d.). Consequently, China faces a number of such problems in transforming the new pharmaceutical patent protection system into domestic law. Second, China has added provisions with respect to the abuse of patent rights and patent open license in the 2020 Patent Law. Article 20 of the 2020 Patent Law provides that: “Patent applications and the exercise of patent rights shall adhere to the principle of good faith. Patent rights shall not be abused to damage the public interest or the lawful rights and interests of any other person. Any abuse of patent rights to preclude or restrict competition, which constitutes a monopolistic act, shall be handled in accordance with the Anti-monopoly Law of the People’s Republic of China.” Competition laws and policies are considered to be able to effectively prevent anti-competitive behaviors such as price collusion, unreasonable restrictions on new technologies, and hindering companies of generics from entering the market, which lead to rising drug prices (Haoran 2019). Currently, China’s regulation of pharmaceutical monopoly is still in its infancy, and the provisions in the Anti-monopoly Law of the People’s Republic of China are not detailed. Therefore, some scholars suggest that drug price monopoly should be taken as the key for identifying the role of the government and the market to improve the operational framework for regulating pharmaceutical monopoly and maintaining the healthy and stable development of the pharmaceutical industry (Jing 2018). Additionally, in order to promote the exploitation and application of patents, Articles 48-52 concerning the open license system are added in the 2020 Patent Law. Article 50 provides that: “Where a patentee voluntarily files a written declaration with the patent administrative department of the State Council, indicating its willingness to permit any entity or individual to exploit its patent and specifying the royalty payment methods and rates, the patent administrative department of the State Council shall make an announcement and implement an open license.” In order to encourage more patentees to voluntarily implement the patent opening license, Paragraph 2 of Article 51 further provides that: “During the period of implementation of the open license, the patent annuity paid by the patentee shall be reduced or waived accordingly.” Whether these newly added provisions will have a positive impact on drug accessibility remains to be proved in practice. Third, China has improved the regulations of a compulsory license system for pharmaceuticals. As early as 1984, China enacted the Patent Law which provided provisions on compulsory licensing, and which has been constantly amended and improved in 1992, 2000 and 2008 Patent Law amendments. In 2012, the China National Intellectual Property Administration issued the revised Measures on Compulsory Patent Licensing to provide detailed provisions on the conditions and procedures for application of various compulsory licensing. From foreign practice, in terms of solutions to domestic public health, the most significant and operable compulsory licensing is the compulsory licensing under national emergencies or abnormal circumstances or for the public interest. Therefore, the Opinions on Reform and Improvement of Policies on Guarantee of Supply and Use of Generic Drugs (the 2018 Opinions) was issued in 2018, which first defines the “abnormal circumstances which threaten the public sanitary and health security” as “national emergencies or abnormal circumstances or for the public interest” (General Office of the State Council 2018). It also provides that the causes of such circumstances included not only an outbreak of major and serious infectious diseases or other abrupt public health events, but also the shortage of drugs for the prevention or treatment of major and serious diseases. “Major and serious diseases” include not only infectious diseases, but also other non-infectious diseases such as cancer. In addition, on the basis of Article 6 of the Measures on Compulsory Patent Licensing, the 2018 Opinions further clarified that the competent departments of the State Council for implementation of compulsory licensing shall be National Health Commission which works together with the Ministry of Industry and Information Technology and National Medical Products Administration. After the signing of the Phase One Agreement, some scholars argued that the patent linkage system and drug data protection may pose obstacles to the implementation of the compulsory patent license, affecting the timely resolution of the public health crisis, and suggested to further improve the compulsory license system for pharmaceutical patents, to build an effective link between the pharmaceutical patent linkage system and patent compulsory license system, and to provide limits and exceptions to the drug data protection (Fuen 2020). Last, China has launched drug pricing and procurement reform. In recent years, China has undertaken reforms around drug prices in order to meet the needs of patients. For instance, the National Healthcare Security Administration (NHSA), established in 2018, will supervise health insurance across both urban and rural populations. The NHSA releases the work plan for the adjustment of the National Reimbursement Drug List (NRDL) each year. Innovative drugs and urgently needed imported drugs with higher prices will be included through negotiations. In 2019, for example, of the 97 drugs successfully negotiated, 70 new drugs had price reductions by an average of 60.7 per cent (news.china.com 2019). The aforementioned Gilead’s Sovaldi, was approved for marketing in China in 2017, priced at 23,000 RMB. In 2019, through NHSA’s negotiations, Sovaldi was included in the NRDL and the price was reduced 4,368 yuan, a reduction of 81 percent (Gilead 2017). Meanwhile, China removed import tariffs on cancer drugs on May 1, 2018 and lowered the value added tax (VAT) on May 3, 2018 (General Office of the State Council 2018). Furthermore, China released the National Pilot Plan of Centralized Drug Procurement in 2019 and launched a new round of drug pricing and procurement reform. The reform was coined the “4+7” procurement reform, which implemented in 4 municipalities (Beijing, Shanghai, Tianjin and Chongqing) and 7 cities (Guangzhou, Shenzhen, Xi’an, Dalian, Chengdu, Xiamen). One of the purposes of the reform is to significantly lower drug prices and reduce the patients’ burden of drug costs.